K041583

JUL 22 2004

510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

Name of Firm:	Innovasis, Inc. 997 East 3900 South, Suite 103 Salt Lake City, Utah 84124
510(k) Contact:	Brent A. Felix Same address as above
Trade Name:	PEEK Cement Restrictor "X-Box"
Common Name:	Cement Restrictor
Classification:	Prosthesis, Hip, Cement Restrictor. Class II (see 21CRF, Sec. 888.3300)
Device Product Code:	JDK. The Panel code is 87.
Substantially Equivalent Devices:	Spinal Concepts, Inc. (K031837, K031318, & K021719) Medtronic Sofamor Danek (K0010528)

Device Description:

The INNOVASIS 'X-Box' PEEK Cement Restrictor is an implant system for use as a non-load bearing 'cement plug' in orthopedic surgery.

The design of the X-Box include rectangular components of different cross-sectional sizes to accommodate various configurations in the midsection femoral/tibial diaphyseal canal. These various size components will aid in placement and retention of the device in the medullary canal in order to prevent the migration of PMMA cement into the canal for patients receiving orthopedic cemented femoral hip or tibial total knee components. The X-Box is a hollow, PEEK material, rectangular frame with fenestrated sides and exterior ribs.

The device is intended to be used in conjunction with standard PMMA bone cement.

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Intended Use:

The INNOVASIS 'X-Box' PEEK Cement Restrictor is intended for use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial canal in hip stem and total knee replacement.

This device is not intended for any spinal indications. The safety and effectiveness of this device when implanted in the spine have not been established

Material:

The Innovasis 'X-Box' PEEK Cement Restrictor is made from PEEK –OPTIMA™ (Polyetheretherketone) material according to ASTM F 2026-00 with embedded 6-4 Alloy Titanium (ASTM F 136) wires as radiological markers.

These materials are proven to be biocompatible as implant materials.

Performance Data:

No mechanical tests were performed to support this application. The Innovasis PEEK Cement Restrictor is a non-load bearing device.

Basis of Substantial Equivalence:

The Innovasis 'X-Box" PEEK Cement Restrictor is similar to the predicate Spinal Concepts, Inc. (K031837, K031318, & K021719) and Medtronic Sofamor Danek (K010528) with respect to technical characteristics and performance.

Summary of Safety and Effectiveness:

The Innovasis "X-Box" PEEK Cement Restrictor system is shown to be safe and effective for use as a cement plug for use in orthopedic total hip and knee implant replacements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2004

Mr. Brent A. Felix
President
Innovasis, Inc.
997 East 3900 South
Suite 103
Salt Lake City, Utah 84124

Re: K041583
Trade/Device Name: PEEK Cement Restrictor "X-Box"
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: JDK
Dated: June 9, 2004
Received: June 11, 2004

Dear Mr. Felix:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INNOVASIS, INC
997 East 3900 South, Suite 103
Salt Lake City, Utah 84124
(801) 557-1445
(801) 424-2097 Fax

510(k) NUMBER: K041583
DEVICE NAME: **PEEK CEMENT RESTRICTOR**
INDICATIONS FOR USE:

The INNOVASIS 'X-Box' PEEK Cement Restrictor is intended for use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial canal in hip stem and total knee replacement.

This device is not intended for any spinal indications. The safety and effectiveness of this device when implanted in the spine have not been established.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter-Use_____

(Per 21 CFR 801.109) (Optional Format)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041583

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